Evaluation of the potential for and clinical impact of increased ALT in patients using the AbbVie 2-DAA or 3-DAA Regimens in a real world setting

First published: 06/07/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS13832

Study ID

33238

DARWIN EU® study

No

Study countries

Canada

Germany

Israel

United States

Study description

A prospective, observational cohort study of patients with HCV treated with AbbVie 2-DAA or 3-DAA regimens and enrolled in the HCV-TARGET disease registry. This design allows the determination of the differences in clinical outcomes related to hepatotoxicity between patients with and without ALT elevations, identification of associated risk factors, and assessment of the clinical impact of these elevations. The longitudinal design allows for the examination of the clinical impact on treatment course and explores potential risk factors for clinical events of interest. Patients are to be followed for SVR12, potential relapse, and the clinical outcomes of interest for 6 months after the end of treatment. Anonymized patient records from the registry will be the cohort source. Enrollment will begin upon protocol approval and include data retrospectively compiled from patients who were treated with the AbbVie regimens since Jan2015, until the required sample size is reached, approx. Oct2019.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 61 centres are involved in the study

Networks

HCV-TARGET: Hepatitis C Therapeutic Registry and Research Network

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/05/2016

Study start date

Actual: 31/01/2019

Date of final study report

Planned: 30/01/2020

Actual: 15/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p15421-protocol-pmos-abstract.pdf (57.75 KB)

p15421-protocol-pmos FINAL_Redacted.pdf (200.83 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

P15-421

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Evaluate and characterize ALT elevations and obtain more information regarding off-label use, contraindicated medication use, and data in populations with limited information for the AbbVie DAA regimen in the real world setting. The impact of ALT elevation on outcome of treatment including specific hepatic outcomes will be examined.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Viekira Pak, Technivie

Medical condition to be studied

Chronic hepatitis C

Population studied

Short description of the study population

Patients with HCV treated with AbbVie 2-DAA or 3-DAA regimens and enrolled in the HCV-TARGET disease registry.

Criteria for the selection of patients are as follows:
Inclusion Criteria:
1. Anonymized records of consecutive patients in the HCV-TARGET database who are at least 18 years of age, males and females, all races and ethnicities.
2. Have a diagnosis of hepatitis C virus infection and be treated with the AbbVie 2-DAA or 3-DAA regimen.
3. Have at least one dose of the AbbVie 2-DAA or 3-DAA regimen outside of a clinical trial.
4. Have a baseline ALT laboratory value as defined by HCV-TARGET prior to start of the AbbVie 2-DAA or 3-DAA regimen and a least one ALT laboratory value after the date of the start of the regimen and during the treatment interval.
5. Treated for hepatitis C infection at a site in the US, EU, Canada, or Israel.

Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Hepatic impaired

Renal impaired

Estimated number of subjects

875

Study design details

Outcomes

-Difference in proportions of clinical outcomes(liver failure/transplantation/decompensation)hospitalization for liver injury, all cause death)-Proportion of Grade 3+ALT elevations-Difference in proportions of treatment decisions(interruption/discontinuation/completion)-Determine the difference in proportions of clinical outcomes assessed as being at leastpossibly related to DAA therapy, -Assess frequency of off-label use in patients who have received the AbbVie 2-DAA or3-DAA regimen in in a real world setting:i.Use of DAA regimen in patients with genotypes other than HCV GT1 or GT4.ii.Use in other DAA combinations-Assess frequency of use of contraindicated medications in patients during treatment-Proportion of underrepresented patient populations in clinical trials

Data analysis plan

For the statistical analysis of the primary objectives, difference of proportions of subjects with each grade of ALT elevation versus no such elevation and of

patients with clinical outcomes and treatment decisions by Grade 3+ ALT elevation versus no such elevation will be reported along with their 95% confidence intervals. Subgroup analysis of the difference in the proportion of subjects with Grade 3+ elevation versus no such elevation and the difference in proportions of subjects with clinical outcomes according to potential risk factors affecting treatment response included in the primary objective above will be performed. The frequency and proportion of subjects with these clinical outcomes, individually and as a composite occurring within 6 months of stopping the AbbVie regimen will be compared between those who had each grade of ALT elevations versus no such elevation within the treatment interval.

Documents

Study results

p15421-pmos-results-abstract-final-redacted.pdf (1.62 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Study includes retrospective data.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No